

Notice of Allowability	Application No.	Applicant(s)	
	09/522,117	CALDWELL ET AL.	
	Examiner	Art Unit	
	Venkataraman Balasubramanian	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12/04/2003.
2. ☒ The allowed claim(s) is/are 22 and 26-29.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____. |
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DETAILED ACTION

Applicants' response, which included cancellation of claims 21, and 23-25 filed on 12/4/2003, is made of record.

Claims 22 and 26-29 are now pending.

Terminal Disclaimer

The terminal disclaimer filed on 5/8/2003 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S.S. N 08/631,761 and 09/642,351 has been reviewed and is accepted. The terminal disclaimer has been recorded.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

The application has been amended as follows:

1. Insert before the first line of the specification "This application is a continuation US Serial Number 09/098,285 filed on 06/16/1998."

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

In view of applicants' response, particularly assertion based on the Declaration under 37 C.F.R§ 1.132 by Dr. William Caldwell, a) that compounds with a alpha methyl group on the carbon bearing the terminal amine show acceptable binding to the relevant receptors, and b) that such compounds with alpha methyl group had improved resistance to monoamine oxidase, and therefore, had improved half-lives, and c) that the monoamine oxidase inhibition is observed regardless of the stereochemistry at the relevant carbon (alpha to the terminal amine) as seen in Table 5, the prior art 103 rejection over Caldwell et al., US 5,861,423, is deemed as obviated.

Furthermore, applicants' submission of a Terminal Disclaimer has overcome the provisional obviousness-type double patenting rejection over Caldwell et al., U.S.S.N. U.S.S.N 08/631,761 and U.S.S.N 09642,351 09/973,419, made in the previous office action. Hence claims 22 and 26-29 are deemed as patentably distinct.

The pyridinyl compounds with R and S isomers and their hemigalactrate salt useful for activating cholinergic receptor embraced in the instant claims were not found to be anticipated or rendered obvious by the prior art of record. Additional search in the related art area also did not yield any prior art disclosing the pyridinyl compounds of formula shown in claim 22, with R and S isomer, or their hemigalactrate salt embraced in the instant claims. Therefore, the examiner noted that the claims 22 and 26-29 would be in condition for allowance.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is Mukund Shah whose telephone number is (571) 272-0674. If Applicants are unable to reach Mukund Shah within 24-hour period, they may contact James O. Wilson, Acting-SPE of art unit 1624 at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Venkataraman Balasubramanian
Venkataraman Balasubramanian

2/18/2004